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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,403	10/03/2003	Paul J. Hindrichs	293 / 053	1004

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EXAMINER	
SZPIRA, JULIE ANN	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
04/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/678,403	HINDRICHS ET AL.	
	Examiner	Art Unit	
	JULIE A. SZPIRA	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-36,54 and 56-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *17-36,54 and 56-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/25/2009 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-19, 22, 24-32, 35, and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by **Vargas et al. (US 6,371,964).**

Vargas discloses:

17. A connector for use in making a hollow anastomotic connection between a first aperture in a side wall defined by first and second ends of a tubular graft tissue conduit having interior and exterior surfaces and a second aperture in a side wall defined by first

and second ends of a tubular body tissue conduit having interior and exterior surfaces in a patient, the connector comprising: a structure capable of being configured to make the hollow anasomotic connection between the first aperture in the sidewall of the tissue conduit and the second aperture in the sidewall of the tubular body conduit that is substantially annularly continuous but annularly enlargeable about its longitudinal axis (figure 1 item 14 lower part of upper portion 18), the structure including: a first portion (24), that includes first and second groups of members where in the first group of members extends away from the structure (figure 1 item 14 , upper part of upper portion 18), wherein a distal perimeter is defined by at least the first group of members, the first group of members is capable of being configured to penetrate through the exterior surface of the tissue conduit and the interior surface of the graft tissue conduit about the first aperture and to engage the interior surface of the body tissue conduit about the second aperture, and the second group of members (figure 1 lower portion 16) is configured to engage the exterior surface of the graft tissue conduit about the first aperture; and a second portion (any portion proximal to the first group of first members so that there is space between the two portions, "portion" is broad such that it is not limiting in any way) proximal to the portion, wherein a first spacing is defined between at least the first group of first members and the second portion, and wherein the structure is configured to expand from a deformed configuration having a collapsed distal perimeter to an expanded configuration having an expanded distal perimeter (Column 3 Line 20).

18. The connector defined in claim 17, wherein the first and second groups of members are substantially radially aligned with respect to a common axis (figure 1).

19. The connector defined in claim 18, wherein the members of the first group extend distally away from the first portion of the structure and wherein the members of the second group extend proximally away from the first portion of the structure (Figure 1).

22. The connector defined in claim 18, wherein the first group of members at least includes the second group of members so that the first group of members is configured to engage both the graft tissue conduit about the first aperture and the interior surface of the body tissue conduit about the second aperture, so that tissue of the graft tissue conduit can extend from within the lumen the body tissue conduit to outside of the body tissue conduit, and so that body fluid of the patient can flow between the lumen of the graft tissue conduit and the lumen of the body tissue conduit via the connection (functional language with no further structure claimed, no patentable weight over the cited art).

24. A connector for use in making a hollow anastomotic connection between a first aperture in a side wall defined by first and second ends of a tubular graft tissue conduit and a second aperture in a side wall defined by first and second ends of a tubular body

tissue conduit in a patient, the connector comprising: a hollow structure that is substantially annularly continuous but annularly enlargeable about its longitudinal axis and configured for disposition substantially perpendicular to the longitudinal axis of the tubular graft conduit and the tubular body conduit (24), the structure including: a distal axial portion (Figure 1 item 14 lower part of upper portion 18), wherein a plurality of first members (figure 1 item 14 upper part of upper portion 18) extend away from the distal axial portion in an annular array that is substantially concentric with the structure, wherein a distal perimeter is defined by at least a first group of the plurality of first members configured to engage the interior wall of the body tissue conduit about the second aperture, and wherein a second group of the plurality of first members (figure 1 item 14 lower part of upper portion 18) is configured to engage the graft tissue conduit about the first aperture; a proximal axial portion (figure 1 item 14 upper portion of lower part 16), wherein a proximal perimeter is defined by a plurality of second members of the proximal axial portion (figure 1 item 14 lower part of lower portion 16) configured to engage the exterior wall of the body tissue conduit about the second aperture; and a medial axial portion (24 portion not including "structure") between the distal axial portion and the proximal axial portion, wherein an axial spacing is defined between at least the first group of first members and the plurality of second members, and wherein the structure is configured to expand from a deformed configuration having a collapsed distal perimeter and a first axial spacing to an expanded configuration having an expanded distal perimeter and a second axial spacing.

25. The connector defined in claim 24, wherein the medial axial portion is configured to extend in a first direction along the exterior of the graft tissue conduit about the first aperture substantially perpendicular to the longitudinal axis of the graft tissue conduit (functional language, structure not differentiated from the reference).

26. The connector defined in claim 24, wherein the distal axial portion is configured to receive tissue of the graft tissue conduit about the first aperture extending up through the hollow interior of the structure in a direction substantially perpendicular to the longitudinal axis of the graft tissue conduit (functional language, structure not differentiated from the reference).

27. The connector defined in claim 24, wherein the collapsed distal perimeter is smaller than the perimeter of the second aperture (the second aperture refers to the tissue graft, the tissue graft has not been specifically claimed so this claim does not add any structural limitation, however Column 5 Line 43 through Column 6 Line 6 discloses this concept).

28. The connector defined in claim 24, wherein the second axial spacing is smaller than the first axial spacing (figure 2).

29. The connector defined in claim 24, wherein at least the first group of first members and the plurality of second members are configured to resiliently press the graft tissue

conduit and the body tissue conduit into annular contact with one another annularly around the first and second apertures (functional language, structure not differentiated from reference).

30. The connector defined in claim 24, wherein the second axial spacing is substantially equal to the sum of the wall thickness of the graft tissue conduit and the wall thickness of the body tissue conduit (graft tissue and body tissue not specifically part of claimed structure, therefore claim does not include any new limitation, however Column 5 Line 43 through Column 6 Line 6 discloses this concept).

31. The connector defined in claim 24, wherein the first and second groups of first members are substantially radially aligned with respect to the longitudinal axis of the structure (figure 1).

32. The connector defined in claim 31, wherein the first members of the first group extend distally away from the proximal axial portion of the structure and wherein the first members of the second group extend proximally toward the proximal axial portion of the structure (figure 1).

35. The connector defined in claim 31, wherein the first group of first members at least includes the second group of first members so that the first group of first members is configured to engage both the graft tissue conduit about the first aperture and the

interior wall of the body tissue conduit about the second aperture, so that tissue of the graft tissue conduit can extend from within the lumen the body tissue conduit to outside of the body tissue conduit, and so that body fluid of the patient can flow between the lumen of the graft tissue conduit and the lumen of the body tissue conduit via the connection (functional language with no further structure claimed, no patentable weight over the cited art).

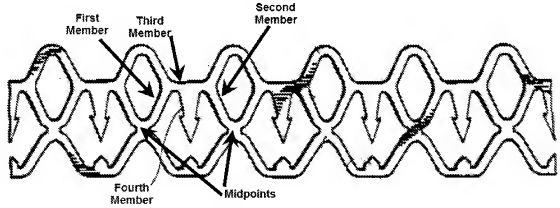
54. Apparatus for producing a hollow anastomotic connection between a first aperture in a side wall defined by first and second ends of a graft tissue conduit and a second aperture in a side wall defined by first and second ends of a body tissue conduit in a patient, comprising: a connector having a structure that is substantially annularly continuous but annularly enlargeable about its longitudinal axis (24), the structure including: a first portion (figure 1 lower part 14 of upper portion 18), wherein the first portion includes a plurality of first members extending away from the structure (figure 1 upper part of upper portion 18), wherein a distal perimeter is defined by at least a first group of the plurality of first members configured to engage the interior wall of the body tissue conduit about the second aperture, and wherein a second group (figure 1 upper part 14 of lower portion) of the plurality of first members is configured to engage the graft tissue conduit about the first aperture; and a second portion (any portion proximal to the first group of first members so that there is space between the two portions, "portion" is broad such that it is not limiting in any way) proximal to the first group of first members, wherein a first spacing is defined between at least the first group of first

members and the second portion, and wherein the structure is configured to expand from a deformed configuration having a collapsed distal perimeter to an expanded configuration having an expanded distal perimeter (Col 3 Line 20); and a delivery tool (Figures 4-6) having a first configuration and a second configuration, wherein the first configuration is configured for retaining a retainable portion of the connector proximal to the first group of first members to deform the connector structure from the expanded configuration to the deformed configuration and to advance the collapsed distal perimeter of the connector into the lumen the body tissue conduit via the second aperture, and wherein the second configuration is configured for releasing the retainable portion of the connector to reform the connector structure from the deformed configuration to the expanded configuration.

Claims 58-61 are rejected under 35 U.S.C. 102(e) as being anticipated by **Swanson et al. (US 6,602,263).**

Regarding claims 58-61, Swanson et al. discloses a connector for use in making a hollow anastomotic connection, the connector comprising: a plurality of hollow cells, wherein the hollow cells are adjoined in an annularly continuous manner, wherein the plurality of hollow cells are annularly enlargeable about a common longitudinal axis, wherein each hollow cell comprises first and second midpoints; a distal portion that includes a top section and a bottom section, wherein: the bottom section includes a first member extending from the first midpoint towards the top section and a second member extending from the second midpoint towards the top section; and the top section includes (I) a third member between the first and second members and (2) a fourth

member that extends from the third member in a direction away from the third member and the hollow cell; and a proximal portion joined to the bottom section of the distal portion at the first and second midpoints; wherein a distal perimeter when the hollow cell is in a deformed configuration is defined by the third members of the plurality of hollow cells and a proximal perimeter different from the distal perimeter is defined by end segments of the proximal portions of the plurality of hollow cells (See Figure Below; Figures 4 and 5), and the fourth member extends in a direction normal to the third member (Figure 4) and in a direction between a normal of the third member and a plane of the first cell (Figure 5), with the end segments oriented in a direction parallel to the third member.



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20, 21, 23, 33, 34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Vargas (US 6,371,964)** and **Lazarus (US 5,397,345).**

Vargas discloses the invention substantially as claimed as stated above. Vargas does not explicitly disclose hooks or barbs on the first members. Lazarus teaches the use of hooks and barbs to engage the tissue or graft wall (Item 70). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Vargas' members to include Lazarus' barbs and hooks. Such a modification would engage the graft material so the vessels remain connected.

Claims 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Vargas (US 6,371,964).**

Vargas discloses the structure of the connector configured for disposition such that the longitudinal axis of the structure is substantially perpendicular to the body conduit, but fails to disclose the axis being substantially perpendicular to the graft conduit.

It would have been obvious to one having ordinary skill at the time to use the tubular graft at an orientation perpendicular to the connector device if the device was being used in a midsection of the graft conduit instead of at the end of the conduit. The claimed orientation of the connector device does not differentiate the device from the structural limitations disclosed in prior art.

Claims 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Vargas (US 6,371,964)** in view of **Swanson et al. (US 6,602,263).**

Vargas discloses the invention substantially as claimed above, but fails to disclose when the structure is in the deformed configuration or expanded configuration, the distal perimeter is different that the maximum proximal perimeter.

However, Swanson et al. teaches the distal and proximal perimeters being different (Figure 5, elements 242 and 240).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have different diameters in the distal and proximal regions to allow for the device to decrease axial spacing of the device to allow for a better approximation of the joined conduits (column 9, lines 1-19).

Response to Arguments

Applicant's arguments filed 2/25/2009 have been fully considered but they are not persuasive.

In response to applicant's arguments, the recitation "connector for use in making a hollow anastomotic connection" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Vargas in view of Lazarus discloses the invention substantially as claimed above, but does not specifically disclose how the device should be used, but it has been held

that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex Parte Masham, 2 USPQ F.2d 1647 (1987).

Furthermore, applicant's argument of the connector being "configured to engage the interior wall of the body tissue" does not render the claim patentable over prior art. Despite the location of use claimed by the applicant, the structure of the device disclosed by Vargas is capable of engaging the interior wall of a body tissue conduit if used in a similar manner as the applicant's device.

It is Examiner's position that the device disclosed by Vargas is capable of performing the tasks claimed by Applicant. Despite the intended use limitations claimed by the Applicant not being *specifically* disclosed by Vargas (as Applicant points out in the arguments), the structure of Vargas can complete the task of attaching two vessels, side by side. The side to side attachment would require another layer of tissue to be interposed within the device, and the device of Vargas is capable of performing that function due to the structure of the device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE A. SZPIRA whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Thursday 9 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie A Szpira/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
4/26/09